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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Stanley M. Crain and Kei-Fei Shen
Appn. No. : 10/037,791
Filed : January 3, 2002
For : METHOD OF SIMULTANEOUSLY ENHANCING ANALGESIC
POTENCY AND ATTENUATING DEPENDENCE LIABILITY
CAUSED BY MORPHINE AND OTHER BIMODALLY-ACTING
OPIOID AGONISTS
Art Unit : 1614
Examiner : J. Reamer

#10
64498
8-28-03

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents
Washington, D.C. 20231

Sir:

"Express Mail" mailing label no. EL 900662508 US

Date of Deposit: December 6, 2002

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner for Patents, Washington, D.C. 20231.

Name: Craig J. Arnold

Signature: Craig J. Arnold

Pursuant to 37 C.F.R. §§§ 1.56, 1.97 and 1.98, applicants enclose the following in connection with the above-identified application:

1. Form PTO/SB/08 (3 sheets) listing Requests for *Ex parte* Reexaminations of U.S. Patent Nos. RE 36,547, 5,767,125, 5,580,876, 6,362,194 and 6,096,756, and new references not of record in the subject application that were cited in the Requests for Reexamination;

2. a copy of the Request for *Ex parte* Reexamination of U.S. Patent No. RE 36,547, including Transmittal (4 pages), Request (86 pages), copy of U.S. Patent No. RE 36,547 (19 pages), copy of List of References Cited by Requester (1 page) and copies of references listed thereon (13 references);

Applicants : Stanley M. Crain and Kei-Fei Shen
Appn. No. : 10/037,791
Filed : January 3, 2002
Page 2

3. a copy of the Request for *Ex parte* Reexamination of U.S. Patent No. 5,767,125, including Transmittal (4 pages), Request (63 pages), copy of U.S. Patent No. 5,767,125 (22 pages), copy of List of References Cited by Requester (1 page) and copies of references listed thereon (11 references);

4. a copy of the Request for *Ex parte* Reexamination of U.S. Patent No. 5,580,876, including Transmittal (4 pages), Request (45 pages), copy of U.S. Patent No. 5,580,876 (21 pages), copy of List of References Cited by Requester (1 page) and copies of references listed thereon (10 references);

5. a copy of the Request for *Ex parte* Reexamination of U.S. Patent No. 6,362,194, including Transmittal (5 pages), Request (72 pages), copy of U.S. Patent No. 6,362,194 (22 pages), copy of List of References Cited by Requester (1 page) and copies of references listed thereon (11 references);

6. a copy of the Request for *Ex parte* Reexamination of U.S. Patent No. 6,096,756, including Transmittal (5 pages), Request (30 pages), copy of U.S. Patent No. 6,096,756 (21 pages), copy of List of References Cited by Requester (1 page) and copies of references listed thereon (9 references); and

7. copies of the references on form PTO/SB/08 not of record in the subject application.

Applicants note that many of the references identified in the Requests for Reexamination are of record in the subject application. The references listed on PTO/SB/08 are believed not to be of record in the subject application, and are believed to be cumulative to the patents and literature publications already considered by the Examiner. Applicants respectfully request that the Examiner consider the Requests for Reexamination of U.S. Patent Nos. RE 36,547, 5,767,125, 5,580,876, 6,362,194 and 6,096,756, including the publications cited therein, in its examination of the subject application.

Applicants : Stanley M. Crain and Kei-Fei Shen
Appn. No. : 10/037,791
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Page 3

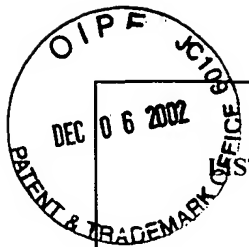
Authorization is hereby given to charge any deficiency or credit any overpayment, or charge any additional extension of time fee necessary to preserve the pendency of the subject application, to Deposit Account No. 01-1785.

Respectfully submitted,

AMSTER, ROTHSTEIN & EBENSTEIN
Attorneys for Applicants
90 Park Avenue
New York, New York 10016
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Dated: December 6, 2002
New York, New York

By Craig J. Arnold
Craig J. Arnold, Reg. No. 34,287



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LIST OF REFERENCES CITED BY REQUESTER

(Use several sheets if necessary)

ATTY. DOCKET NO.

7000-075-999

PATENT

RE 36,547

PATENT OWNER

Albert Einstein College of Medicine of Yeshiva University

ISSUE DATE

February 1, 2000

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AD	4,582,835	4/15/86	Lewis et al.			
	AH	3,879,555	4/22/75	Pachter et al.			
	AI	4,457,933	7/3/84	Gordon et al.			
	AJ	4,935,428	6/19/90	Lewis et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
							YES	NO

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

	AA	Schmidt et al., 1985, "Postoperative pain relief with naloxone. Severe respiratory depression and pain after high dose buprenorphine," Anaesthesia 40:583-586
	AB	Pedersen et al., 1985, "Naloxone - a strong analgesic in combination with high dose buprenorphine," Brit. J. Anaesth. 57: 1045-1046
	AC	Levine et al., 1988, "Potentiation of pentazocine analgesia by low-dose naloxone," J. Clin. Invest. 82(5):1574-77
	AE	Bergman et al., 1988, "Low dose naloxone enhances buprenorphine in a tooth pulp antinociceptive assay," Arch. Int. Pharmacodyn. Ther. 291
	AF	Dum and Herz, 1981, "In vivo Receptor Binding of the Opiate Partial Agonist, Buprenorphine, Correlated with its Agonistic and Antagonistic Actions," Br. J. Pharmac. 74:627-633
	AG	Vaccarino et al., 1989, "Analgesia produced by normal doses of opioid antagonists alone and in combination with morphine," Pain 36:103-09
	AK	Budd, 1987, "Clinical use of opioid antagonists, Balliere's Clinical Anesthesiology 1(4):993-1011
	AL	Goodman & Gilman, 1975, The Pharmacological Basis of Therapeutics, 5th Edition, Macmillan, New York, Chapter 15, p. 273
	AM	Crain & Shen, 1995, Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic co-treatment. Proc Natl Acad Sci U S A. 1995 Nov 7;92(23):10540-10544

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to owner and requester.

LIST OF REFERENCES CITED BY REQUESTER

(Use several sheets if necessary)

ATTY. DOCKET NO.

7000-078-999

PATENT

6,096,756

PATENT OWNER

Albert Einstein College of Medicine of Yeshiva University

ISSUE DATE

August 1, 2000

GROUP

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
AG	4,863.928	9/5/89	Atkinson et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
					YES NO

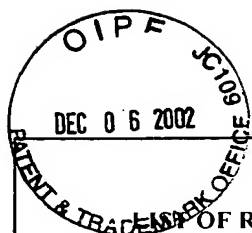
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

AA	Budd K., 1985, "The use of the opiate antagonist, naloxone, in the treatment of intractable pain." Neuropeptides. 5(4-6):419-22.
AB	Budd, 1987, "Clinical use of opioid antagonists". Bailliere's Clinical Anaesthesiology 1:993-1011
AC	Attal et al. 1989, "Behavioural evidence for a bidirectional effect of systemic naloxone in a model of experimental neuropathy in the rat." Brain Res. 494(2):276-84
AD	Kayser et al. 1981, "Dose-dependent analgesic and hyperalgesic effects of systemic naloxone in arthritic rats." Brain Res. 226(1-2):344-8
AE	Kayser et al. 1984, "Further evidence for a bidirectional effect of naloxone on the pain threshold in tolerant and non-tolerant arthritic rats." Neuropeptides. 5(1-3):49-52
AF	Kayser et al. 1986, "Analgesia produced by low doses of the opiate antagonist naloxone in arthritic rats is reduced in morphine-tolerant animals." Brain Res. 371(1):37-41.
AH	Malaise & Franchimont, 1987, "Methods of clinical and biological assessment of rheumatoid arthritis." Scand J Rheumatol Suppl. 65:81-4. Review
AI	Crain & Shen, 1995, Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic co-treatment. Proc Natl Acad Sci U S A. 1995 Nov 7;92(23):10540-10544

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LIST OF REFERENCES CITED BY REQUESTER (Use several sheets if necessary)	ATTY. DOCKET NO.	PATENT
	7000-079-999	5,580,876
	PATENT OWNER Albert Einstein College of Medicine of Yeshiva University	
	ISSUE DATE December 3, 1996	GROUP

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AG	4,457,933	7/3/84	Gordon et al.			
	AD	5,834,477	11/10/98	Mioduszewski			12/8/93

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
							YES NO

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)		
AA	Holmes et al., 1993, "Inhibiting a spinal dynorphin A component enhances intrathecal morphine antinociception in mice," <i>Anesth. Analg.</i> 77(6):1166-73	
AB	Konieczko <i>et al.</i> , 1988, "Antagonism of morphine-induced respiratory depression with nalmefene," <i>Br. J. Anaesth.</i> 61:318-323	
AC	Budd, 1987, "Clinical use of opioid antagonists," <i>Balliere's Clinical Anesthesiology</i> 1(4):993-1011	
AE	Barsan <i>et al.</i> , 1989, "Duration of Antagonistic Effects of Nalmefene and Naloxone in Opiate-Induced Sedation for Emergency Department Procedures, <i>J. Emerg. Med.</i> 7(2): 155-161	
AF	Levine <i>et al.</i> , 1988, "Potentiation of pentazocine analgesia by low-dose naloxone," <i>J. Clin. Invest.</i> 82(5):1574-77	
AH	Crain & Shen, 1995, Ultra-low concentrations of naloxone selectively antagonize excitatory effects of morphine on sensory neurons, thereby increasing its antinociceptive potency and attenuating tolerance/dependence during chronic co-treatment. <i>Proc Natl Acad Sci U S A.</i> 1995 Nov 7;92(23):10540-10544	
AI	Abu-Elheiga <i>et al.</i> , 2001, "Continuous fatty acid oxidation and reduced fat storage in mice lacking Acetyl-coA carboxylase 2," <i>Science</i> 291: 2613-16	
AJ	Goodman & Gilman (eds.), 1975, <i>The Pharmacological Basis of Therapeutics</i> , 5th Edition, Macmillan, New York, Chapter 15, "Narcotic Analgesics and Antagonists" (by J.H. Jaffe and W.R. Martin) pages 245-283	

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